

REMARKS

Claims 1-26 are pending in the present application. In the Office Action mailed October 12, 2006, the Examiner rejected claims 1-12 under 35 U.S.C. §101. The Examiner next rejected claims 16-19 under 35 U.S.C. §112, second paragraph. Claims 1-3, 5-9, 13, 16-19, and 24-26 were rejected under 35 U.S.C. §102(b) as being anticipated by Kruger (USP 6,216,025). Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Takashima (JP363211879). Claims 10-12, 13-15, 20, 21, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Ben-Haim et al. (US Pub. 2002/0065455) “Ben-Haim.” Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Ben-Haim et al., and further in view of Maas, III (USP 6,181,832).

In regard to the rejection under §101, the Examiner stated that the invention as described in claim 1 does not have a practical application because it does not “provide a transformation or reduction of an article to a different state or thing” and does not “produce a useful, concrete, and tangible result.” *Office Action, October 12, 2006, Pg. 3.* Applicant disagrees because, quite simply, claim 1 is a process, which falls squarely within an enumerated category of 35 U.S.C. §101. The “practical application” standards the Examiner refers to were fashioned to address subject matter which does not clearly fall within a category that is expressly set forth in §101, not to further limit those categories already specifically enumerated in §101. *See State Street Bank & Trust v. Signature Financial*, 149 F.3d 1368, 1374-75 (Fed. Cir. 1999)(“it is improper to read limitations into §101 on the subject matter that may be patented where the legislative history indicates that Congress clearly did not intend such limitations”). In other words, the Examiner cannot add strings to what is already statutory. The Examiner cannot say some processes are patentable and others are not, just like an Examiner cannot say some machines are not patentable. Machines and methods are two expressly enumerated categories for patentable subject matter under §101. The Examiner cannot further restrict what the legislature has provided. The MPEP states very clearly that “[i]f USPTO personnel can establish a *prima facie* case that a claim does not fall into a statutory category, the patentability analysis dies not end there,” and then says “USPTO personnel must further continue with the statutory subject matter analysis as set forth below.” MPEP § 2106(IV)(B). Here, the claim clearly falls within one of the four enumerated categories (i.e. a process) and, as such, the MPEP directs that the analysis should stop at this point.

Regardless, even if such new tests were applicable to claims falling within the statutory categories, claim 1 clearly satisfies them. Claim 1 is a “method of diagnostic imaging” including

steps of “acquiring” a first set of data and “determining” a second set of data from the first set of data. Such steps transform a first set of acquired data to a second set of data in the field of diagnostic imaging.

Furthermore, contrary to the allegation of the Examiner, the invention as recited in claim 1 also produces a useful, concrete, and tangible result. According to the Examiner, “to be ‘useful’ [an invention] must satisfy the utility requirement.” *Office Action, October 12, Pg. 3*. However, the utility requirement does not necessitate that a specific, substantial, and credible use be recited in the claim. Rather, a utility is ordinarily described in the Specification. *See MPEP § 2107.02 (“Upon initial examination, the examiner should review the specification to determine if there are any statements asserting that the claimed invention is useful for any particular purpose”)*. There is no requirement that an intended use or utility be wholly recited in a claim. The Specification of the present application clearly sets forth a specific, substantial, and credible use for the invention, “the present invention includes an imaging technique for deriving data that would otherwise have been acquired at inadmissible transducer locations.” *Specification, Pg. 9, lns. 25-26*.

In addition, the invention as recited in claim 1 produces a tangible result in that it changes “articles or materials to a different state or thing.” Claim 1 recites a method of diagnostic imaging that includes the step of “determining a second set of TCT data from the first set of TCT data for a second portion of the measurement surface different from the first portion.” Such a method of imaging is a very practical application which produces real world results - for example, a diagnostic image.

Likewise, the invention as set forth in claim 1 also produces a concrete result. According to the Examiner, to produce a concrete result, an invention must “have a result that can be substantially repeatable.” *Office Action, October 12, 2006, Pg. 4*. With respect to claim 1 in particular, the Examiner merely reiterated the test, stating without any reasoning that “the result can not be substantially repeatable and the process can not substantially produce the same result again.” *Id.* The Examiner cannot say that each time the process of claim 1 is performed, a diagnostic image will not result. Without knowing the Examiner’s basis for questioning the reliability or repeatability of the invention, Applicant cannot address the Examiner’s conclusory argument with any particularity. However, Applicant notes that diagnostic imaging is a well-known art and that images are reliably reproducible according to many inventions including that set forth in claim 1, as discussed throughout the Specification, and as known in the art. The Examiner has not presented any substantive argument to the contrary.

Therefore, the present invention as recited in claim 1 not only falls squarely within a statutory category (a process), but also calls for a method that has a practical application which both transforms a state of matter and produces a useful, concrete, and tangible result (although such is not even necessary for an enumerated statutory category). As such, Applicant respectfully requests withdrawal of the rejection of claims 1-12 under §101.

The Examiner rejected claims 16-19 under 35 U.S.C. §112, second paragraph. Per the comments of the Examiner, claim 16 has been amended to depend from claim 13. Applicant requests that the §112 rejection of claim 16 and the claims that depend therefrom be withdrawn.

Claims 1-3, 5-9, 13, 16-19, and 24-26 were rejected under 35 U.S.C. §102(b) as being anticipated by Kruger. Claim 1 calls for, in part, determining a second set of TCT data from a first set of TCT data. Claim 13 calls for, in part, a TCT imaging system having a computer programmed to derive, from acquired data, unacquired data for an imaging object. Claim 24 calls for, in part, generating a first TCT dataset from the ultrasonic emissions and deriving a second TCT dataset from the first TCT dataset.

Kruger teaches specific arrangements of multiple transducers on a rotatable imaging bowl for measuring acoustic waves produced in tissue when the tissue is exposed to electromagnetic radiation. *Kruger, Abstract.* Kruger describes acoustic shielding techniques to minimize stray echoes and sources of noise, techniques for cancelling noise, modulation of the time between imaging pulses to randomize the effect of acoustic echoes, and a filtering technique applied to compensate for the frequency response of the transducers. *Id., Col. 3., lns. 15-26.* “The aim is to reconstruct some property of the breast from an ensemble of pressure measurements made externally to the breast.” *Id., Col. 10, lns. 18-20.* “An array of sixty-four acoustic transducers 33 is located within imaging bowl 14 in tank 16 (sic).” *Id., Col. 6, lns. 1-2.* The transducers should be evenly spaced across the array, and are positioned in connection to Fig. 6. *Id., Col. 6, lns. 3-5.*

Fig. 6 illustrates the positions of the transducers in the spiral array (some are shown in phantom). The position (r, θ, Φ) as is illustrated in Fig. 6. Each of the N transducers 33 is on the spherical surface (at a constant radius R), located at a unique (θ, Φ) coordinate, and is oriented on the surface with its axis passing through the center C of the radium of curvature of the spherically curved surface of imaging bowl 14. The Φ positions of the transducers 33 range from a minimum angle of Φ_{min} , approximately 16.6 degrees, to a maximum angle of Φ_{max} , approximately 72 degrees. It is desirable to maximize this range of angles, i.e., so that $\Phi_{max} - \Phi_{min}$ is as large as possible, since doing so will enhance the extent to which features in the imaged tissue can be reconstructed in multiple dimensions. (In some embodiments, $\Phi_{max} - \Phi_{min}$ typically must be less than 45°; however, in the embodiment of FIG. 6, $\Phi_{max} - \Phi_{min}$ approaches 90°.) *Id., Col. 9, lns. 34-51.*

Fig. 3 illustrates a pair of dome-shaped shells 31a and 31b having an air gap 32 formed between them, thus forming an acoustic barrier that is electromagnetically transparent. *Id., Col. 7, lns. 11-23.* Fig. 5A illustrates details of analog data acquisition circuitry that is positioned near transducer 33 to maximize signal strength and improve noise immunity. *Id., Col. 8, lns. 27-31.* Thus, Kruger teaches arrangements of transducers and techniques for measuring acoustic waves in tissue when the tissue is exposed to electromagnetic radiation. Nowhere does Kruger teach or suggest determining a second set of imaging data from a first set of data.

The Examiner alleged that the element “deriving a second TCT dataset from the first TCT dataset” was present at Fig. 12A, Item 98. *Office Action, October 12, 2006.* However, Item 98 merely teaches plotting values in two or three dimensions to generate a tissue image. *Kruger, Fig. 12A.* Step 98 is described in the specification as “the image data is plotted in two or three dimensions so that the tissue may be visualized.” *Id., Col. 14, lns. 12-13.* Nowhere in the cited location does this make any reference to “deriving a second TCT dataset from the first TCT dataset.”

In summary, not only does Kruger not teach or suggest determining a second set of TCT data from a first set of TCT data, it also does not teach deriving a second TCT dataset from a first TCT dataset.

As such, Applicant believes that which is called for in claims 1, 13, and 24 is not taught or suggested by Kruger and requests allowance thereof. In particular, Kruger does In light of claims 2-3, 5-9, 16-19, and 25-26 depending from what are believed otherwise allowable claims, Applicant requests allowance of claims 2-3, 5-9, 16-19, and 25-26 based on the chain of dependency.

Claims 10-12, 13-15, 20, 21, and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kruger in view of Ben-Haim. Claim 13 is discussed above. Claim 20 calls for, in part, a computer programmed to acquire TCT data from an imaging object, and determine TCT data corresponding to a desirable transducer location about the imaging object not having a transducer location.

Kruger is distinguished above, and Ben-Haim does not resolve Kruger’s deficiencies with respect to the rejected claims..

Ben-Haim teaches a locating system for determining the location and orientation of an invasive medical instrument relative to a reference frame. *Ben-Haim, Abstract.* The position and orientation of a distal end of a catheter are ascertained by use of two or three antennas, such as

radiators 18, 20, and 22. *Id. Par. 103.* The three radiators are driven by a radiator driver 24 and, along with a signal processor 26, provide “a display or other indication of the position and orientation of the distal end 15 on a monitor 27.” *Id., Par. 105.* “[T]he field equations are derived specifically for each embodiment and are dependent on the geometry and characteristics of the radiators.” *Id., Par. 147.* In the preferred embodiment where the radiators are coils, for a coil with N turns, radius R , and current I , a series of vector equations are generated wherein a radial and tangential component are described. *Id., Pars. 147-148.* The tangential component includes an expression, $P_n(x)$, which is a Legendre Polynomial of degree n which may be calculated recursively through the method described. *Id., Pars. 149-153.* Thus, the field sensed by a remote sensor results in equations having known and unknown variables for any given coil. *Id., Pars. 154-155.* In the embodiment having three sensors, the technique described results in an overdetermined series of nine equations and six variables and, with nine sensor readings, the unknowns may be numerically solved for by using, for instance, a Newton-Raphson method for non-linear systems, and “[t]he location sensor position and orientation are displayed on monitor 27.” *Id., Pars. 158-159.* Thus, Ben-Haim describes obtaining a location and orientation of an invasive medical instrument using a numerical solution that includes a Legendre Polynomial.

Nowhere does Kruger or Ben-Haim or a combination thereof teach or suggest deriving, from acquired data, unacquired data for an imaging object. Nowhere does Kruger or Ben-Haim, or a combination thereof teach or suggest determining TCT data corresponding to a desirable transducer location about an imaging object not having a transducer location.

Accordingly, that which is called for in claims 13 and 20 is not taught or suggested by Kruger or Ben-Haim or a combination thereof. In light of claims 10-12, 14-15, 21, and 23 depending from what are believed otherwise allowable claims, Applicant requests allowance of claims 10-12, 14-15, 21, and 23 based on the chain of dependency.

Therefore, in light of at least the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1-26.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,

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